



9-26-04

Attorney's Docket No.: 17103-003001/1457

1614

[Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Robert S. Osbakken et al. Art Unit : 1614
Serial No. : 09/942,959 Examiner : Donna Jagoe
Filed : August 31, 2001 Confirmation No.: 7962
Customer No.: 20985
Title : AEROSOLIZED ANTI-INFECTIVES, ANTI-INFLAMMATORIES, AND
DECONGESTANTS FOR THE TREATMENT OF SINUSITIS

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (2 page), cited references, return postcard, and a check for the requisite fee of \$180.00 for filing in connection with the above-captioned patent application

- ☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

[Signature]
Stephanie L. Seidman
Reg. No. 33,779

Attorney Docket No. 17103-003001/1457

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CERTIFICATE OF MAILING BY "EXPRESS MAIL"
"Express Mail" Mailing Label Number EV 399295332 US
Date of Deposit September 17, 2004
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

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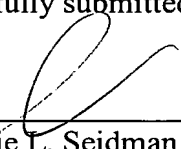
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after receipt of a First Office Action on the Merits for the above-captioned application, the filing fee of \$180 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (2 pages) and copies of the cited references are provided herewith in connection with the above-captioned application.

The documents listed on the Form PTO-1449 are in the English language with the exception of items L and W. Item L is in the Spanish language and an English translation is

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Stephanie L. Seidman

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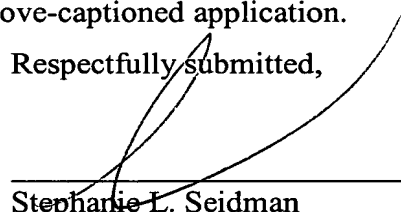
attached. Item W, which is in the Japanese language, is provided with an English language abstract on the last page of the article. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed item is necessary.

Since the last Supplemental Information Disclosure Statement was filed on May 12, 2004, no additional co-pending applications need be made known to the Examiner.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,



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Reg. No. 33,779

Attorney Docket No. 17103-003001/1457

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Substitute Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
17103-003001 / 1457Application No.
09/942,959**List of Patents and Publications for Applicant's
Information Disclosure Statement**

(37 CFR §1.98(b))

Applicant
Robert S. Osbakken et al.Filing Date
August 31, 2001Group Art Unit
1614**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A	2002/0061281	05/23/02	Osbakken <i>et al.</i>	424	43	08/31/01
	B	2002/0102294	08/01/02	Bosch <i>et al.</i>	424	450	11/12/98
	C	2002/0197212	12/26/02	Osbakken	424	45	07/09/02
	D	2003/0031631	02/13/03 A1	Osbakken	424	45	08/28/02
	E	4,438,100	03/20/84	Baslev <i>et al.</i>	424	104	12/28/81
	F	5,789,391	08/04/98	Jacobus <i>et al.</i>	514	51	07/03/96
	G	5,883,084	03/16/99	Peterson <i>et al.</i>	514	78	06/08/98
	H	5,958,897	09/28/99	Jacobus <i>et al.</i>	514	49	01/09/98
	I	5,972,904	10/26/99	Jacobus <i>et al.</i>	514	51	01/09/98
	J	5,981,506	11/09/99	Jacobus <i>et al.</i>	514	47	01/09/98

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	K	03/020219	03/13/03 A2	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	L	Guevara <i>et al.</i> , "[The Ambulatory Aerosol Therapy in the Treatment of Chronic ENT Pathology," <i>Anales O.R.L. Iber. Amer.</i> XVIII, 3:231 – 238 (1991) (In Spanish, English summary on last page of article)
	M	Kondo <i>et al.</i> , "Transitional Concentration of Antibacterial Agent to the Maxillary Sinus via a Nebulizer," <i>Acta Otolaryngol. Suppl.</i> 525:64-67 (1996)
	N	Negley <i>et al.</i> , "RinoFlow™ Nasal Wash and Sinus System as a mechanism to deliver medications to the paranasal sinuses: Results of a radiolabeled pilot study," <i>ENT Journal</i> , 78(8):550-554 (1999)
	O	O'Riordan <i>et al.</i> , "Effect of Nebulizer Configuration on Delivery of Aerosolized Tobramycin," <i>Journal of Aerosol Medicine</i> 20(1):13-23 (1997)
	P	Press Release "SinusPharma Forms Strategic Partnership with Priority Healthcare Corporation; Innovative Chronic Sinusitis Therapy Takes Center Stage" (September 18, 2003) http://www.sinuspharmacy.com/news_sinuspharmaprioritypartnership.html [accessed on 09/08/04]
	Q	Press Release "Scripps Memorial Hospital's Chief of Otolaryngology Develops Usage Algorithm for Intranasal Nebulized Medications for Chronic Sinusitis" (February 12, 2003) http://www.sinuspharmacy.com/presswahl.html [accessed on 09/08/04]

Examiner Signature

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
17103-003001 / 1457Application No.
09/942,959**List of Patents and Publications for Applicant's
Information Disclosure Statement**

(37 CFR §1.98(b))

Applicant
Robert S. Osbakken et al.Filing Date
August 31, 2001Group Art Unit
1614**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	R	Press Release "SinusPharmacy Adds Nasal Irrigation Option to SinuNEB System" (September 18, 2002) http://www.sinuspharmacy.com/pressirrigator.html [accessed on 09/08/04]
	S	Press Release "Patent for Sinusitis Treatment Awarded to SinusPharma" (June 11, 2003) http://www.sinuspharma.com/investors/releases/sinuspharma-patent.html [accessed on 09/08/04]
	T	Press Release "Study Finds Nebulized Antibiotics Effective Against Chronic Sinusitis" (September 17, 2002) http://www.sinuspharmacy.com/pressnebulizedsinusitis.html [accessed on 09/08/04]
	U	Press Release "SinusPharmacy Announces Breakthrough in Treating Chronic Sinusitis" (September 25, 2000) http://www.sinuspharmacy.com/press001.html [accessed on 09/08/04]
	V	<i>Stedman's Medical Dictionary</i> , 27 th Ed. P. 1644 (1999), Lippincott Williams & Wilkins, Baltimore MD
	W	Yokota <i>et al.</i> , "[Antibacterial Activities of Cefmenoxime against recent fresh clinical isolates from patients of sinusitis]," <i>Japanese Journal of Antibiotics</i> :48(5):602-609 (1995) (In Japanese, English abstract on last page of article)

Examiner Signature

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